

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|---|-------------|----------------------|-------------------------|-----------------|
| 09/731,519 | 12/06/2000 | R. David Rines | 9558 | |
| 7590 02/10/2004 | | | EXAMINER | |
| Rines and Rines | | | RIMELL, SAMUEL G | |
| 81 North State Street Concord, NH 03301 | | | ART UNIT | PAPER NUMBER |
| | | | 2175 | |
| | | | DATE MAILED: 02/10/2004 | 4 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| <u>•</u> | | | | | | |
|--|---|--|--|--|--|--|
| | Application No. | Applicant(s) | | | | |
| | 09/731,519 | RINES, R. DAVID | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Sam Rimell | 2175 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | | | | | | |
| | action is non-final. | | | | | |
| | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-22 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-22 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomposed and any objection to the Replacement drawing sheet(s) including the correct of the section of the section is objected to by the Examine 11). | epted or b) objected to by the drawing(s) be held in abeyance. Settion is required if the drawing(s) is ob | e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d). | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some coll None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) | | sam Rimell Primary examiner | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Di 5) Notice of Informal F 6) Other: | (PTO-413) | | | | |

Application/Control Number: 09/731,519

Art Unit: 2175

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-2, 4-12 and 14-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Bassett, Jr. et al. ('241).

Claim 1: FIG. 2 discloses the generation of an image derived from the analysis of genes or proteins. Col. 5, lines 1-13 describes the usage of a scanning device which scans the image. The image is then stored in a database (106). The image can subsequently be retrieved for various forms of analysis (col. 11, lines 35-38). The images are standardized in the sense that they are all two dimensional and in color. The reference also recognizes additional image standards, such as JPEG (col. 5, line 1).

Claim 2: FIG.2 discloses the generation of an image derived from the analysis of genes or proteins. The image is a pattern of spots. The pattern is gene specific (see FIG. 6 where the pattern is specific to a particular gene name). The image may be derived from a polymerase chain reaction that involves an electrophoresis separation, typically occurring a gel (col. 7, lines 61-65). A scanning device scans the image and stores the scan in a database (106). As seen in FIG. 1, multiple users (108, 116) can input the spot patterns into the database. Multiple users can retrieve the data from the database as well (col. 19, lines 16-17).

Page 3

Application/Control Number: 09/731,519

Art Unit: 2175

<u>Claim 4:</u> As seen in FIG. 1, all communications with the database (106) are made by entities (108, 116) that are external in relation to the database (106).

Claim 5: Communications may be achieved over the Internet (112 in FIG. 1).

<u>Claims 6:</u> Any equipment used in a laboratory to achieve the electrophoresis described at col. 7, lines 61-66 reads as a customized kit for identifying genes. Also note applicant's statement on page 7, line 10 of the specification, where applicant states: "Apart from the resulting spot pattern images displayed on the gel, the details of such PCR-electrophoresis operations form no part of the novelty of the present invention."

<u>Claim 7:</u> Electrophoresis equipment is customized for identifying genes. Without any description as to how the kit is customized, the claim reads on any electrophoresis equipment. Also not applicant's statement on page 7, line 10, of the specification.

<u>Claim 8:</u> Any electrophoresis equipment can be used for identifying unknown genes.

<u>Claim 9:</u> The image comparison permitted by the system of Bassett, Jr. et al. can assist in the identification of mutations (col. 42, lines 22-24).

<u>Claim 10:</u> The system of Bassett, Jr. et al. permits the evaluation of specific drug candidates on cells, thus aiding in identifying target cells affected by these drugs (col. 24, lines 60-62).

Claim 11: Col. 19, lines 13-21 describe the access of the database (or databases) by external researchers. Since the system is available over the Internet (112 in FIG. 1), the information in the databases has a global reach.

Claim 12: See remarks for claim 1.

Claim 14: See remarks for claim 4.

Application/Control Number: 09/731,519

Art Unit: 2175

Claim 15: See remarks for claim 5.

Claim 16: See remarks for claims 2 and 6.

Claim 17: Col. 19, lines 13-21 describe the presence of other databases maintained by other research entities, which read as "protein databases", since they also contain the same biological response data as the database (106). The "biological response software" (304) reads as the "protein modeling software" since the biological response, such as the pattern of dots in FIG. 2, provides a visualization model of gene based or protein based materials.

<u>Claims 18-20:</u> Col. 19, lines 13-21 describe other genomic references in the form of other research entities, "biological response software" that reads as "protein modeling software" and other databases (col. 19, line 14 in particular).

<u>Claims 21-22:</u> Each of the images are the same two dimensional color images. The images are thus standardized (they all have the same 2-D color format) and the standard dictates the size (two dimensions) and contrast (full color images).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bassett, Jr. et al. ('241).

Claims 3 and 13 differ from the claims in that it does not specifically disclose multiplex polymerase chain reaction by two dimensional scanning. Basset, Jr. et al. only disclose polymerase chain reaction in general terms.

Art Unit: 2175

However, multiplex polymerase chain reaction by two dimensional scanning is well known in the art by applicant's admission in the disclosure (page 1, second paragraph of specification).

Bassett. Jr. et al. also states that other systems are within the spirit and scope of the invention (col. 5, lines 30-35).

It would therefore have been obvious to one of ordinary skill in the art to modify Bassett, Jr. et al. to obtain data by multiplex polymerase chain reaction by two dimensional scanning as a choice of design well known in the art by applicant's own admission and applicable to Bassett Jr. et al. as another system for generating biological responses (col. 5, lines 30-35 of Bassett Jr. et al.).

Remarks

Applicant's arguments have been considered.

Applicant argues that the two dimensional spot patterns of Bassett, Jr. are not "standardized", and points to pages 4, 8, 9 and 10 of the original specification for a definition of the term "standardized" in reference to image display formats. Examiner finds two discussions of the term "standardized" in applicant's original specification.

One of these discussions is at page 9, which refers to "standardized formatting software" but provides no details on the meaning of the term "standardized".

A more detailed discussion of the term appears at page 8, in the first paragraph, where applicant states that images are formed into a "...standard form (size, contrast. etc.). From reviewing these remarks, it is clear that size and contrast are general standards that may be used. In the case of Basset, Jr. et al. it is clear that contrasting colors are used to depict the genes

Application/Control Number: 09/731,519

Art Unit: 2175

according to a standard contrasting format. Thus, using applicant's own definition, the Bassett,

Jr. et al. fully anticipates the claimed standards.

However, the first paragraph of page 8 in applicant's specification only recite size and contrast as examples of standards that may be applied. It is clear from a reading of this

discussion that other examples of standards may be used (see page 8, lines 3-4, where applicant

uses the phrase "size, contrast, etc."). Thus, the alterative examples of standards, such as two

dimensional display formats and the JPEG format are also considered to be image display

standards consistent with applicant's intended meaning of the term "standards".

This office action is non-final.

Any inquiry concerning this communication should be directed to Sam Rimell at

telephone number (703) 306-5626.

Sam Rimell

Primary Examiner

Page 6

Art Unit 2175